

01-16-04



SIU 7397
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Campbell

Serial No. 10/684,436

Filed October 27, 2003

For THERAPEUTIC USE OF METHIONINE FOR THE TREATMENT OR PREVENTION
OF MUCOSITIS

January 15, 2004

COMMISSIONER FOR PATENTS

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SIR:

INFORMATION DISCLOSURE STATEMENT

* In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits copies of the references listed on the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicant believes that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

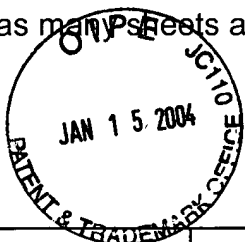
Respectfully submitted,

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PTO/SB/08A		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/684,436		
		Filing Date	October 27, 2003		
		Confirmation Number	not yet assigned		
		First Named Inventor	Campbell		
		Group Art Unit	not yet assigned		
		Examiner Name	not yet assigned		
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OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	1.	BENEVENGA, Norlin J., "Toxicities of Methionine and Other Amino Acids", <i>Journal of Agricultural and Food Chemistry</i> , January-February 1974, pages 2-9, Volume 22, Number 1, American Chemical Society, Easton, Pennsylvania	
	2.	BLOM, Henk J. et al., "Transamination of methionine in humans", <i>Clinical Science</i> , 1989, pages 43-49, Volume 76, Medical Research Society, London	
	3.	CAMPBELL, Kathleen C.M. et al., "D-Methionine protects against cisplatin damage to the stria vascularis", <i>Hearing Research</i> , 1999, pages 13-28, Volume 138, Elsevier Science, Amsterdam	
	4.	CAMPBELL, Kathleen C.M. et al., "D-Methionine provides excellent protection from cisplatin ototoxicity in the rat", <i>Hearing Research</i> , December 1996, pages 90-98, Volume 102, Number 1/2, Elsevier Science, Amsterdam	
	5.	DONNELLY, J.P. et al., "Can anything be done about oral mucositis?", <i>Annals of Oncology</i> , 2003, pages 505-507, Volume 14, European Society for Medical Oncology	
	6.	FRIEDMAN, Mendel, "Chemistry, Nutrition, and Microbiology of D-Amino Acids", <i>Journal of Agricultural and Food Chemistry</i> , September 1999, pages 3457-3479, Volume 47, Number 9, The American Chemical Society, Easton, Pennsylvania	
	7.	GHIBELLI, L. et al., "Rescue of cells from apoptosis by inhibition of active GSH extrusion", <i>Faseb Journal</i> , April 1998, pages 479-486, Abstracts Part II, Volume 12, Number 5, Federation of American Societies for Experimental Biology, Bethesda, Maryland	
	8.	KAJI, Hiroshi et al., "Urinary 3-Methylthiopropionate Excretion and the Effect of D- or L-Methionine Ingestion Studied in Healthy Subjects", <i>Chemical Pathology and Pharmacology</i> , April 1987, pages 101-109, Volume 56, Number 1, P.J.D. Publications, Westbury, New York	
	9.	KIES, Constance et al., "Comparative Value of L-, DL-, and D-Methionine Supplementation of an Oat-based Diet for Humans", <i>The Journal of Nutrition</i> , July 1975, pages 809-814, Volume 105, Number 7, The American Institute of Nutrition, Bethesda, Maryland	

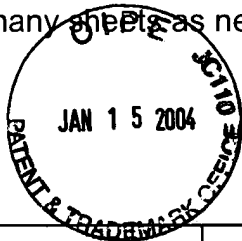
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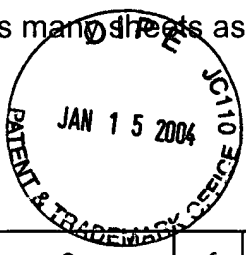
	10.	LU, S., "Regulation of Hepatic Glutathione Synthesis", <i>Seminars in Liver Disease</i> , 1998, pages 331-334, Volume 18, Number 4, Thieme Medical Publishers, Inc., New York	
	11.	NATIONAL RESEARCH COUNCIL., Recommended Dietary Allowances, 1980, Ninth Edition, Washington D.C.	
	12.	RESER, David et al., "L- and D-Methionine Provide Equivalent Long Term Protection Against CDDP-Induced Ototoxicity <i>In Vivo</i> , with Patial <i>In Vitro</i> and <i>In Vivo</i> Retention of Antineoplastic Activity", <i>Neuro Toxicology</i> , October 1999, pages 731-748, Volume 20, Number 5, Intox Press, Inc., Redfield, Arkansas	
	13.	SONIS, S.T., "Mucositis as a biological process: a new hypothesis for the development of chemotherapy-induced stomatotoxicity", <i>Oral Oncology</i> , January 1998, pages 39-43, Volume 34, Number 1, Pergamon	
	14.	SONIS, Stephen T. et al., "Editorial - Prevention of mucositis in cancer patients", <i>Journal of the National Cancer Institute - Mucosal Injury in Cancer Patients: New Strategies for Research and Treatment</i> , 2001, pages 1-2, Number 29, U.S. Dept. of Health and Human Services, Washington D.C.	
	15.	STEGINK, Lewis D. et al., "Effects of Equimolar Doses of L-Methionine, D-Methionine and L-Methionine-dl-Sulfoxide on Plasma and Urinary Amino Acid Levels in Normal Adult Humans", <i>The Journal of Nutrition</i> , July 1986, pages 1185-1192, Volume 116, Number 7, The Wistar Institute of Anatomy and Biology, Philadelphia, Pennsylvania	
	16.	STEKOL, Jakob A. et al., "Pathological Effects of Excessive Methionine in the Diet of Growing Rats", <i>The Journal of Nutrition</i> , May 1962, pages 81-90, Volume 77, Number 1, The Wistar Institute of Anatomy and Biology, Philadelphia, Pennsylvania	
	17.	WALSER, Mackenzie et al., "The Effect of Keto-analogues of Essential Amino Acids in Severe Chronic Uremia", <i>The Journal of Clinical Investigation</i> , January 1973, pages 678-690, Volume 52, Number 1, The American Society for Clinical Investigation, Inc., New York, New York	
	18.	WHO EXPERT COMMITTEE, The Use of Essential Drugs: Eighth report of the WHO Expert Committee (including the revised Model List of Essential Drugs), December 1997, WHO Technical Report Series 882, World Health Organization, Geneva	

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	19.	WINGARD, John R., "Infectious and Noninfectious Systemic Consequences", <i>National Cancer Institute Monographs - Consensus Development Conference on Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment</i> , 1990, pages 21-26, Number 9, U.S. Department of Health and Human Services, Bethesda, Maryland	
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